Surgical treatment of defecation disorders

Valorisation addendum

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Introduction

Faecal incontinence (FI) has gained a significant increase in treatability during the last 20 years. The introduction of the Dynamic Graciloplasty (DGP) by Baeten and simultaneously by Williams has made a huge impact on the whole colorectal community. Together with the Artificial Bowel Sphincter, these two surgical procedures offered patients dealing with faecal incontinence, an opportunity to augment their defective anal sphincter. Before this period of surgical innovations, the standard treatment of a defective sphincter was an anal repair, however the results of this procedure failed in time. Also conservative therapy, e.g. constipating medicine and (biofeedback) pelvic behavioural therapy wasn't providing the success that patients with severe faecal incontinence needed. These patients frequently ended with a definitive stoma. The introduction of Sacral Nerve Modulation (SNM) also known as Sacral Nerve Stimulation (SNS) provided a minimal invasive procedure with less morbidity to treat faecal incontinence. As a spinoff of this treatment modality it also seemed possible to treat idiopathic constipation by means of SNM. This thesis focused on the surgical treatment of faecal incontinence and the treatment of idiopathic constipation by means of SNM.

Epidemiology and etiology of faecal incontinence

Faecal incontinence is a common health care problem, affecting 5% to 10% of community-dwelling adults with 1% to 2% experiencing huge impact on daily activities. It aggravates with advancing age and disability. It is a disorder, which is particularly embarrassing and socially unacceptable, and many patients do not seek professional help. Therefore, a huge underestimation of the problem can be expected. The part of the population that seeks help is merely “the tip of the iceberg”. Faecal incontinence has a negative impact on physical and psychological health and lifestyle, with social activity restriction in many instances.
The aetiology of faecal incontinence is divers and multi-factorial. It is a combination of sphincter pressure, anorectal sensation and compliance, rectal storage function, faecal consistence and brain function. Trauma to the sphincter complex is one of the most frequent causes of FI. It can be due to birth trauma or iatrogenic trauma in anal surgery. Bols et at found that 3rd of 4th degree ruptures contribute significantly to postpartum faecal incontinence. The anorectal sensation and compliance can be altered due to inflammatory processes, as seen in Crohn’s disease and ulcerative colitis. Nerve damage post-partum can cause diminished sensation of rectal filling. Altered anorectal storage function, as seen after low anterior resection for rectum carcinoma, can contribute to faecal incontinence. Due to chronic inflammatory bowel diseases the liquidity of the faeces increases, which decreases the “grip” on the faecal

matter and can lead to incontinence. Neurologic diseases, e.g. spina bifida, multiple sclerosis, can cause FI. Disorders of brain function, e.g. after cerebrovacular events, can cause FI.
The above-mentioned multi-variability makes it challenging to solve the problem of FI. A holistic approach is necessary to solve every aspect of the problems encountered by FI. Preferably this should take place in specialised centres, where dedicated teams operate closely together. Such teams ideally consist of a colorectal surgeon, gynaecologist, urologist, gastro-enterologist, psychiatrist and physiotherapist.

Epidemiology of constipation

Based on a recent systematic review, the prevalence of constipation is very variable, ranging from 2.5% to as high as 79%. However, the variability in prevalence can be due to a lack of uniformity in the definition of constipation. When applying the Rome III criteria, the prevalence varies between 11% and 18%. It is present in all age groups and is most commonly seen in women and non-Caucasians. Other symptoms such as bloating and pain can be present. Different subtypes have been distinguished; colonic inertia, outlet obstruction, functional constipation. The outlet obstruction can be caused by pelvic floor dyssynergia, but also by anatomical obstructions such as a rectal prolapse, intussusception, enterocele and/or rectocele, but also by a rectum carcinoma. Thorough investigation is necessary since the treatment of the above-mentioned entities is very different.
Sacral nerve modulation has shown some promising results in the study that has been addressed in this manuscript. Is has still to earn its placed in the treatment algorithm. During a modified Delphi method this specialists from several European centres have stated that SNM for constipation is less effective than when used in FI and further research is needed.

Valorisation

For the addendum of valorisation five questions can be used a guideline:
- What is the socio-economic relevance off the research results (relevance)?
- For whom, outside the peer researchers, are the results relevant (target population)?
- Which concrete services/products can be obtained (products)?
- What is the innovation value of the results (innovation)?
- What are the marketing strategies that can be applied (planning and realisation)?

Socio-economic relevance

Functional bowel disorders are difficult entities to treat successfully. Usually patients are referred back and forth between different specialists thereby increasing costs and decreasing effectiveness. The MUMC has acknowledged this problem several years ago and a Pelvic care Unit was constructed to discuss these patients once a week in a systematic manner. Another important milestone was the construction of the Medpsych Unit, since functional bowel disorders and simultaneous psychological problems go hand in hand.
Years of investigation in the MUMC has made it possible to objectify the results of sacral neuromodulation. A line of consecutive researchers were able to seamlessly extract data from large cohort files. Van Wunnik et al were able to demonstrate that the introduction of SNM in the surgical management algorithm for faecal incontinence was both more effective and less costly than DGP or ABS without SNM. They concluded that it justified adequate funding for SNM for patients with faecal incontinence. The Dutch healthcare insurance companies were able to define a DOT and therefore made it possible to deliver sacral neuromodulation to a broader public. In the beginning it was only paid out of the academic budget of the MUMC.
The role for sacral neuromodulation in constipation has yet to be explored more thoroughly. Untill this date not much is known about the cost effectiveness. A research protocol has been made in the MUMC to address this problem. Is has been send for evaluation to the Zorg Instituut Nederland and ZonMw.

Target population

The results of this manuscript are relevant to patients with faecal incontinence and constipation. It can be used during information days for patient associations. Furthermore, it can be relevant for medical device corporations to develop less costly devices then the ones that are used today. This thesis showed that patients with faecal incontinence due to a sphincter defect can be treated successfully with sacral neuromodulation without restoring the anatomy first. This reduces the costs and burden for the patient since a sphincter repair is no longer a prerequisite for sacral neuromodulation.

Products

There are no new products that have been developed with the results of this thesis

Innovation and future

The past 30 years in the treatment of functional bowel disorders, especially for patients with faecal incontinence, have been very innovative. Were in the past a colostomy was the only treatment option, nowadays several treatment modalities are

available. We have learned that the artificial bowel sphincter can be successfully implemented in a surgical strategy to treat faecal incontinence. However we have also learned that the morbidity of this procedure is high. Other large colorectal centres have had the same experience, decreasing the initial enthusiasm. American Medical Systems, producer of the artificial bowel sphincter, is incorporated by Boston Scientific this year. This has led to the production stop of the neosphincter by the end of this year. Therefore it will be no longer possible to treat new patients or perform revisions of existing systems.

The dynamic graciloplasty has gained its role in the treatment of faecal incontinence. It was popular during the nineties of the previous century. A lot of patients have been treated with this procedure worldwide. It was the start of the era of electrical augmentation. Initial results were good, but results declined over time as shown in chapter two. To this date not much surgeons are able to perform the procedure. However with large anal sphincter defects and cloacal deformities, this procedure remains the only viable one. This can be said the same for faecal incontinent patient born with anal atresia and anal pull trough procedures. The only alternative for all of them is a colostomy.

The major advantage of sacral neuromodulation over the above mentioned surgical procedures, is the fact that it is less invasive for the patients with less morbidity and similar success rates. How ever it is not successful in all patients. The key lies in better patient selection and fully understanding the working mechanism of neuro-modulation. Several studies to address this issue are started in the nearby future in the MUMC. Chapter 7 discusses the future perspectives as well.